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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,695	08/20/2008	Hermona Soreq	30394	4082

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
09/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,695	SOREQ ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Group I, claim(s) 11-23, 33-57, and 65-77, drawn to methods of preventing or treating diseases or disorders associated with amyloid fibril formation.

Group II, claim(s) 24-32, drawn to methods of identifying BChE derived peptides capable of preventing or reversing amyloid fibril formation.

Group III, claim(s) 58-64, drawn to methods of limiting or reducing an inflammatory reaction.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-III lack unity of invention because the groups do not share the same or corresponding technical feature. Groups I-III are directed to materially different methods achieving materially different results. In vivo treatment methods are materially different than in vitro testing of peptides. Treatment methods drawn to preventing or treating diseases or disorders associated with amyloid fibril formation achieve materially different results than treatment methods drawn to limiting or reducing an inflammatory reaction. Further, the X reference cited in the International Search Report is evidence that the invention as claimed lacks the same or corresponding special technical feature and therefore lacks unity of invention.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Applicants' product claims 1-10 will be joined with the elected method. See 37 CFR 1.475(b)(2).

2. If Applicants elect the invention of Group I, the following restriction requirement among the peptides identified by SEQ ID NO is imposed:

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Peptides, compositions comprising the same, and methods of using the same, in which the peptide is one of SEQ ID NOS:1, 2, and 8-20302.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Although the peptides share a common structure of a peptide backbone, the common structure is not a significant structural element because it represents only a small portion of the compound structures and does not constitute a structurally distinctive portion. Further, the compounds of these groups do not belong to a recognized class of chemical compounds. In addition, the X reference cited in the International Search Report is evidence that the invention as claimed lacks the same or corresponding special technical feature and therefore lacks unity of invention.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

It should be noted that the examiner is not requiring an election of species among the more than 20,000 identified amino acid sequences, but rather is restricting among the amino acid

sequences. Additional amino acid sequences will not be re-joined and examined if the elected SEQ ID NO is determined to be allowable over the prior art of record.

3. If Applicants elect the invention of Group II, the following restriction requirement among the peptides identified by SEQ ID NO is imposed:

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Peptides, compositions comprising the same, and methods of using the same, in which the peptide is one of SEQ ID NOS:1 and 8-20302.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Although the peptides share a common structure of a peptide backbone, the common structure is not a significant structural element because it represents only a small portion of the compound structures and does not constitute a structurally distinctive portion. Further, the compounds of these groups do not belong to a recognized class of chemical compounds. In addition, the X reference cited in the International Search Report is evidence that the invention as claimed lacks the same or corresponding special technical feature and therefore lacks unity of invention.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

It should be noted that the examiner is not requiring an election of species among the more than 20,000 identified amino acid sequences, but rather is restricting among the amino acid

sequences. Additional amino acid sequences will not be re-joined and examined if the elected SEQ ID NO is determined to be allowable over the prior art of record.

4. If Applicants elect the invention of Group III, the following restriction requirement among the peptides identified by SEQ ID NO is imposed:

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Peptides, compositions comprising the same, and methods of using the same, in which the peptide is one of SEQ ID NOS:1 and 8-20302.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Although the peptides share a common structure of a peptide backbone, the common structure is not a significant structural element because it represents only a small portion of the compound structures and does not constitute a structurally distinctive portion. Further, the compounds of these groups do not belong to a recognized class of chemical compounds. In addition, the X reference cited in the International Search Report is evidence that the invention as claimed lacks the same or corresponding special technical feature and therefore lacks unity of invention.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

It should be noted that the examiner is not requiring an election of species among the more than 20,000 identified amino acid sequences, but rather is restricting among the amino acid

sequences. Additional amino acid sequences will not be re-joined and examined if the elected SEQ ID NO is determined to be allowable over the prior art of record.

5. If Applicants elect the invention of Group I, the following election of species requirement is imposed:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows: Methods of preventing or treating the particular diseases or disorders recited in instant claims 14-18.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The claimed methods lack unity of invention because the groups do not share the same or corresponding technical feature. The methods involve treating individuals exhibiting different symptoms and different underlying biochemical defects, and involve achieving different results in these individuals, i.e. preventing or treating different diseases or disorders. Further, the X reference cited in the International Search Report is evidence that the invention as claimed lacks the same or corresponding special technical feature and therefore lacks unity of invention.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: 1-23, 33-57, and 65-77.

6. REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
September 22, 2010